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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,676	04/08/2002	Sam Fong Yau Li	2577-118	7819
6449	7590	09/09/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C.			LUCAS, ZACHARIAH	
1425 K STREET, N.W.			ART UNIT	PAPER NUMBER
SUITE 800			1648	
WASHINGTON, DC 20005				

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/019,676	LI ET AL.
	Examiner	Art Unit
	Zachariah Lucas	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 July 2004.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 73-102 is/are pending in the application.

4a) Of the above claim(s) 92 and 93 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 73-91 and 94-102 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. In the prior action, mailed on March 25, 2004, claims 43-61, 63-65, and 67-72 were pending and rejected. Claims 62 and 66 were withdrawn from further consideration as being drawn to nonelected inventions. These claims were cancelled in the Response of July 26, 2004, and replaced with new claims 73-102, which are drawn to substantially the same subject matter.
2. Currently, claims 73-91, and 94-102 are pending. The claims are under examination to the extent that they read on the elected inventions, including generic claims thereto. Claims 92 and 93 are withdrawn as directed to non-elected inventions.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. **(Prior Rejection- Withdrawn)** Claims 43-61, 63-65, and 67-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It was unclear what is meant by a metal modified crystal. In view of the cancellation of the rejected claim language, the rejection is withdrawn.
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Maintained)** Claims 43-61, 63-65, and 67-72 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims were described in the prior action. Although the previously pending claims have been cancelled and replaced with new claims 73-91, and 94-102 which describe substantially the same subject matter. The claims were rejected because the Applicant has not enabled the practice of the claimed methods wherein the Pz crystals are not metal modified. I.e., the claims did not require the presence of metal electrodes indicated by the art to be essential to the practice of the claimed method. Although the Applicant has amended the claims such that they are now silent as to the presence of the electrodes, it is not clear that the claims do not read on the previously rejected embodiments (i.e. wherein the Pz crystals are not metal modified such that they comprise the electrodes indicated to be essential to the device used in the claims). The rejection is therefore maintained.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **(Prior Rejection- Maintained)** Claims 43, 45, 47-50, 52, 53, 59, 60, 63, 67-69, and 71 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Bastiaans et al., (U.S. Patent 4,735,906, of record in the April 2002 IDS), in view of Larue (U.S. Patent

5,705,399) and Thorns (U.S. Patent 5,510,241). These claims have been cancelled and replaced with claims 73, 74, 76, 78-81, 83, 84, 90, 91, 95, 97, and 99-101. The claims read on methods for performing immunodiagnostic tests against *S. enteritidis* comprising attaching a antigen, or antibody against an antigen, of the bacterium to a piezoelectric (Pz) crystal, exposing the crystal to a sample, and determining if the pathogen is present based on changes to the resonant frequency of the crystal before and after such contact. The new claims include a requirement that the crystal was previously used in a test with a negative result for the target infectious agent.

The Applicant traverses the rejection on the grounds that the prior art references cited by the Examiner do not render obvious the use of Pz crystals which were previously used in a test which was negative for the infectious agent. In particular, the Applicant argues “Although the Bastiaans and Larue references refer to washing and regenerating crystals for further use after obtaining a positive result, there is no disclosure of reusing crystals already tested against negative samples, and thus no recognition of the advantages for veterinary applications of methods having this feature.” This argument is not found persuasive.

As was indicated in the prior action, each of the Bastiaans and Larue references teaches that, after use, the devices may be cleared of bound antibody/antigen using compounds with high ionic strength (including sodium chloride solutions), or low ph. Bastiaans, col. 6 lines 17-30; Larue, col. 16 lines 43-48. The Bastiaans reference further teaches that such clearance provides the disclosed device with the benefits of reusability. Id. See also, Larue, col. 16, *supra* (also teaching the benefit of reusability). Because the reference indicates that the device is reusable with such clearing, it would be apparent to those in the art that the device could be reused after a test, whether the result was positive or negative. While the reference used the example where the

“substance that was detected” can be removed by the cleaning, from the indications of reusability in general, it would have been obvious to those in the art to clear the device as suggested whether the test was positive or not. The reference does not teach that the reusability is dependant upon a positive result in the prior tests. In view of these teachings, the Applicant’s arguments in traversal are not found persuasive.

It is noted that the Applicant asserts the benefits of speed, simplicity, and reusability. However, these benefits are also recognized in the teachings of the references. See e.g., Bastiaans, col. 6, supra. (referring to the simpler and faster operation of the disclosed device, and the benefits of reusability). Thus, these additional advantages do not appear to distinguish the claimed invention from the teachings of the references. Nor has the Applicant pointed out any feature of the claimed invention that provides unexpected advantages over the devices suggested by the prior art. The Applicant’s arguments regarding the additional advantages are therefore not found persuasive.

For the reasons above, and the reasons of record, the rejection is maintained over the new claims.

9. **(Prior Rejection- Maintained)** Claims 43-45, 47-50, 52, 53, 59, 60, 63, 64, and 67-72 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Bastiaans et al., (U.S. Patent 4,735,906, of record in the April 2002 IDS), in view of Larue (U.S. Patent 5,705,399) and Rajashekara et al. (WO 98/03656). These claims have been cancelled and replaced by new claims 73-76, 78-81, 83, 84, 90, 91, 95-97, and 99-102. The Applicant traverses

the rejection for the same reasons as described above. For the reasons above, the traversal is not found persuasive and the rejection is maintained over the new claims.

10. **(Prior Rejection- Maintained)** Claims 46, and 54-58 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either Thorns or Rajashekara, as these references were applied against the previous versions of the above claims, and of Willner et al. (WO 98/40739, Willner I- of record in the April 2002 IDS). Claims 46 and 54-58 have been cancelled, and replaced by new claims 77, and 85-89. The Applicant traverses the rejection for the same reasons as described above. For the reasons above, the traversal is not found persuasive and the rejection is maintained over the new claims.

11. **(Prior Rejection- Maintained)** Claim 51 was rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either Thorns or Rajashekara as applied to the previous pending versions of the above claims, and further in view of Willner et al. (WO 97/04314, Willner II- of record in the April 2002 IDS). This claim has been replaced by new claim 82. The Applicant traverses the rejection for the same reasons as described above. For the reasons above, the traversal is not found persuasive and the rejection is maintained over the new claim.

12. **(Prior Rejection- Maintained)** Claims 61 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either Thorns or Rajashekara as applied to the previous pending versions of the above claims, and further in view

of Masten et al., J Bacteriol 175: 5359-65 and in view of Protein Accession CAA78777. These claims have been replaced by new claims 94 and 98. The Applicant traverses the rejection for the same reasons as described above. For the reasons above, the traversal is not found persuasive and the rejection is maintained over the new claim.

***Conclusion***

13. No claims are allowed.
14. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

Tom-Moy et al., U.S. Patent 6723516. This reference provides teachings relevant to the claimed inventions, and appears to be redundant in part to the references cited above.

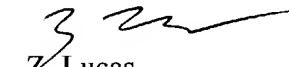
15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Z. Lucas  
Patent Examiner

  
9/7/04  
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